Remarks

Claims 1-43 were pending in this application. Claims 1 and 2 have been amended herein. Claims 3-42 are withdrawn from consideration. Of the withdrawn claims, claims 11, 13, 15, 18, 19, 20, and 42 are amended to parallel the scope of the pending claims and claims 21, 25, 26, and 27 are amended to correct matters of form. Claims 12, 14, 16, 17, and 39 are canceled and new claims 44-48 are added.

Support for the amendment of claims 1, 11, 13, 15, 18, 19, 20, and 42 can be found in the specification at least at page 27, lines 18-19. Further support for the amendment of claim 1 can be found in the specification at least at page 28, lines 11-14. Support for new claim 44 can be found in the specification at least at page 44, lines 23-34. Support for new claims 45-47 can be found in the specification at least at page 28, lines 11-14. Support for new claim 48 can be found in the specification at least at page 10, lines 25-28 and page 18, lines 29-37.

No new matter is added by these amendments. Unless specifically stated otherwise, none of these amendments is intended to limit the scope of any claim. Applicants reserve the right to prosecute any removed subject matter in a continuation application. After entry of this amendment, **claims 1-11, 13, 15, 18-38, and 40-48 are pending**. Reconsideration of the pending claims is respectfully requested.

Restriction Requirement

Applicants acknowledge, under protest, that the election of Group 1 (claims 1 and 2), directed to a purified p28ING5 tumor suppressor protein, is made final. The claims of Groups 2-14 (claims 3-43) are currently withdrawn.

In the Response to Restriction Requirement dated December 4, 2006, Applicants contended that the claims were linked by a special technical feature, namely a tumor suppressor protein comprising amino acid residues 1-13 and 227-240 of SEQ ID NO: 2, because the cited reference (Marcu *et al.*; U.S. Patent No:6,066,474, issued May 23, 2000) did not disclose amino acid residues 227-240 of SEQ ID NO: 2. The Office now alleges that the claims are not so linked because another reference, Azimzai *et al.* (U.S. Patent Application Publication

2006/0127894, published June 15, 2006), discloses a protein that is identical to SEQ ID NO: 2 of the present invention, except that a proline, instead of a serine, is at position 170. Azimzai *et al.* claims the benefit of U.S. Provisional Application No. 60/317,913, filed September 7, 2001. Attached herewith is a Declaration Under 37 C.F.R. §1.131 by Curtis C. Harris, Makoto Nagashima, and Masayuki Shiseki. The Declaration and attached Exhibit A demonstrate that, prior to September 7, 2001, the inventors of the subject application had conceived and reduced to practice a human polypeptide with a sequence comprising amino acid residues 1-13 and 227-240 of SEQ ID NO: 2. Thus, in view of the Declaration Under 37 C.F.R. §1.131, Azimzai *et al.* is not available as prior art in this case. Without this reference, the claims are indeed linked by a special technical feature. As unity of invention exists, at least among Groups 1-12 in the present application, it is inappropriate to subject claims 1-37 and 40-42 to a requirement for restriction. Applicants respectfully request that the requirement be withdrawn, that Groups 1-12 be rejoined, and that the corresponding claims be examined in the current case. This specific argument was not raised previously because Azimzai *et al.* had not been cited.

Applicants also wish to point out that claim 43 (directed to a composition comprising the tumor suppressor protein of claim 1) was added in the Response submitted on December 4, 2006. As claim 43 is directed to a composition comprising the protein of Group 1 and depends from claim 1, this claim should be included in Group 1 and should not be withdrawn, as indicated by the current Office action. In the event that the Examiner does not withdraw the restriction requirement, Applicants respectfully request that the Examiner at least examine claim 43, along with claims 1 and 2.

Information Disclosure Statement (IDS)

Applicants thank the Examiner for reviewing and initialing the Information Disclosure Statement filed on July 22, 2004.

Claim Objection

Claim 2 is objected to as being dependent on a rejected claim. Without conceding that claim 1 is not patentable, claim 2 has been amended to be rewritten herein so it is in independent

form. In light of the amendment of claim 2, Applicants respectfully request that the objection of claim 2 be withdrawn and that this claim be allowed.

Claim Rejections Under 35 U.S.C. §112, first paragraph

Written Description

Claim 1 is rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor had possession of the invention at the time the application was filed. Applicants traverse this rejection.

The Office action alleges that the specification does not provide an adequate written description of the genus of p28ING5 tumor suppressor proteins of claim 1 because "[o]ne species of p28ING5 tumor suppressor protein, does not sufficiently describe the [claimed] genus of p28ING5 tumor suppressor proteins" (Office action at page 5). However, the Office action states that "the instant specification may provide an adequate written description of the genus of p28ING5 . . . by describing structural features common to the members of the genus" (page 4).

As established in *Ex parte Parks*, "adequate description under the first paragraph of 35 U.S.C. 112 does not require literal support for the claimed invention. . . . Rather, it is sufficient if the originally-filed disclosure would have conveyed to one having ordinary skill in the art that an appellant had possession of the concept of what is claimed" *Ex parte Parks,* 30 USPQ2d 1234, 1236-37 (B.P.A.I. 1993) (emphasis added). Moreover, the MPEP at §2163 states that "[w]hat is conventional or well known to one of skill in the art need not be disclosed in detail. See *Hybritech Inc. v. Monoclonal Antibodies, Inc.,* 802 F.2d at 1384, 231 USPQ at 94 (Fed. Cir. 1986) . . . If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met. See, e.g. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116 (Fed. Cir. 1991); *Martin v. Johnson,* 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972) (stating "description need not be in *ipsis verbis* [i.e., "in the same words"] to be sufficient")."

Claim 1, as amended, is directed to: "A purified p28ING5 tumor suppressor protein having a sequence comprising amino acid residues 1-13 and [residues] 222-240 of SEQ ID NO: 2, wherein the sequence has at least 85% sequence identity over the entire length of SEQ ID NO: 2." The subject matter claimed now defines the genus of a purified p28ING5 tumor suppressor protein in terms of i) specific amino acid residues at both ends of the protein and ii) 85% sequence identity across the entire length of SEQ ID NO: 2.

Applicants submit that the claimed subject matter, including p28ING5 variant sequences, is clearly described in the specification. First, the specification discloses the p28ING5 amino acid sequence (SEQ ID NO: 2), as well as portions of SEQ ID NO: 2, set forth as amino acids 1-13 (see, for example, page 20, line 16) and 222-240 (for example, page 27, line 19). Second, the specification clearly discloses that variants of SEQ ID NO: 2 may be defined in terms of their sequence identity (page 28, lines 11-14). The specification further describes that mutation, substitution, or deletion of residues within conserved regions, such as a p28ING5 nuclear localization signal (corresponding to residues 222-240 of SEQ ID NO: 2) can alter tumor suppressor activity (specification at page 27, lines 12-21). In addition, Figure 12 discloses an alignment of five ING family protein sequences and identifies residues corresponding to consensus positions (darkened boxes). Thus, Applicants submit that the pending claims are sufficiently described by the specification and the scope of the claimed genus is not unreasonably overbroad.

Applicants further submit that a person of ordinary skill could easily envision sequence variants of a p28ING5 tumor suppressor protein, based on the teachings of the specification and the provision of the sequence itself. Thus, the original disclosure clearly conveys that Applicants had possession of the claimed invention, and certainly of the concept of what is currently claimed.

In light of the above arguments, Applicants submit that claim 1 is clearly described by the specification. Applicants request that this rejection under 35 U.S.C. §112, first paragraph, be withdrawn.

New matter

Claim 1 is also rejected because the Office action alleges that the amino acid residue limitation of residues 227-240 of SEQ ID NO: 2 is new matter. Applicants respectfully traverse this allegation.

SEQ ID NO: 2 is a 240 amino acid sequence which is clearly disclosed in the sequence listing. Inherent in such a sequence are residues 227 and 240. Thus, a portion of SEQ ID NO: 2, as defined by residues 227-240, is sufficiently described by the specification. However, solely to advance prosecution in this case, claim 1 has been amended to be directed to "amino acid residues 1-13 and 222-240 of SEQ ID NO: 2," which finds literal support in the specification at page 27, line 19. In light of the above arguments and amendment, Applicants respectfully request that this rejection of claim 1 be withdrawn.

Claim Rejections Under 35 U.S.C. §102(e)

Claim 1 is rejected under 35 U.S.C. §102(e) as allegedly anticipated by Azimzai *et al.*, which has an alleged priority date of September 7, 2001. Applicants respectfully traverse this rejection.

Azimzai *et al.* claims the benefit of U.S. Provisional Application No. 60/317,913, filed September 7, 2001. Attached herewith is a Declaration Under 37 C.F.R. §1.131 by inventors Curtis C. Harris, Makoto Nagashima, and Masayuki Shiseki. The Declaration and attached Exhibit A (GenBank Accession No. AAL68979) demonstrate that, "[p]rior to September 7, 2001, a human polypeptide corresponding to a sequence comprising amino acid residues 1-13 and 227-240 of SEQ ID NO: 2 was isolated and the amino acid sequence of this polypeptide was determined" (Declaration, paragraph 4). Thus, prior to September 7, 2001, the inventors had conceived and reduced to practice a human polypeptide corresponding to a sequence comprising amino acid residues 1-13 and 227-240 of SEQ ID NO: 2. Applicants respectfully submit that Azimzai *et al.* is not available as prior art in the current case, particularly with regard to claim 1, either as rejected (227-240 of SEQ ID NO: 2) or as submitted herein (222-240 of SEQ ID NO: 2).

In view of the Declaration Under 37 C.F.R. §1.131, reconsideration and withdrawal of this rejection is respectfully requested.

Conclusion

Based on the foregoing amendments and arguments, the claims are in condition for allowance and notification to this effect is requested. If for any reason the Examiner believes that a telephone conference would expedite allowance of the claims, please telephone the undersigned at the number listed below.

Respectfully submitted,

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